

§ 1314.42 Self-certification fee; time and method of fee payment.

(a) A regulated seller must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of \$21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated seller shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

[73 FR 79323, Dec. 29, 2008]

§ 1314.45 Privacy protections.

To protect the privacy of individuals who purchase scheduled listed chemical products, the disclosure of information in logbooks under § 1314.30 is restricted as follows:

(a) The information shall be disclosed as appropriate to the Administration and to State and local law enforcement agencies.

(b) The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.

(c) A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

[71 FR 56024, Sept. 26, 2006, as amended at 77 FR 4238, Jan. 27, 2012]

§ 1314.50 Employment measures.

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving

or related to such products or controlled substances.

Subpart C—Mail-Order Sales**§ 1314.100 Sales limits for mail-order sales.**

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in a single calendar day sell to any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products.

(b) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in any 30-day period sell to an individual purchaser more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, or 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1314.101 Training of sales personnel.

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for preparing and packaging scheduled listed chemical products for delivery to purchasers through the Postal Service or any private or commercial carrier or who deal either directly or indirectly with purchasers by obtaining payments for the products, the regulated person has submitted to the Administration a self-certification that all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated person to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated person maintains a copy of each self-certification and all

§ 1314.102

records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

[76 FR 20523, Apr. 13, 2011]

§ 1314.102 Self-certification.

(a) A regulated person who makes a sale at retail of a scheduled listed chemical product and is required under §1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must submit to the Administration the self-certification referred to in §1314.101(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in §1314.101(a), the certification includes a statement that the regulated person understands each of the requirements that apply in this part and agrees to comply with the requirements.

(b) When a regulated person files the initial self-certification, the Administration will assign the regulated person to one of twelve groups. The expiration date of the self-certification for all regulated persons in any group will be the last day of the month designated for that group. In assigning a regulated person to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of self-certification. After the initial certification period, the regulated person must update the self-certification annually.

(c) The regulated person who makes a sale at retail of a scheduled listed chemical product and is required under §1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must provide a separate certification for each place of business at which the regulated person sells scheduled listed chemical products at retail.

[76 FR 20523, Apr. 13, 2011]

§ 1314.103 Self-certification fee; time and method of fee payment.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under §1310.03 of this chapter to submit a re-

21 CFR Ch. II (4–1–12 Edition)

port of the sales transaction to the Administration must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of \$21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated person shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

[76 FR 20523, Apr. 13, 2011]

§ 1314.105 Verification of identity for mail-order sales.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under §1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must, prior to shipping the product, receive from the purchaser a copy of an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B). Prior to shipping the product, the regulated person must determine that the name and address on the identification correspond to the name and address provided by the purchaser as part of the sales transaction. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

(b) If the product is being shipped to a third party, the regulated person must comply with the requirements of paragraph (a) to verify that both the purchaser and the person to whom the product is being shipped live at the addresses provided. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.